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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ANITA LAUX

Plaintiff,

v.

MENTOR WORLDWIDE, LLC; and DOES 1-10, inclusive

Defendants.

Case No. 2:16-cv-01026-ODW(AGR)

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT [59]

I. INTRODUCTION

Plaintiff Anita Laux initiated this action against Defendant Mentor Worldwide, LLC, on December 29, 2015, in Ventura County Superior Court. (Compl., ECF No. 1-2.) On February 12, 2016, Defendant removed this case to United States District Court for the Central District of California. (ECF No. 1.) Before the Court now is Defendant's Motion for Summary Judgment. (Mot., ECF No. 59.) Having considered the parties' submissions, and for the reasons that follow, the Court **GRANTS** Defendant's Motion.[1]

[1] After considering the moving papers, the Court deems the matter appropriate for decision without oral argument. Fed. R. Civ. P. 78(b); C.D. Cal. L.R. 7-15.

II. FACTUAL BACKGROUND

Defendant is a manufacturer of saline filled inflatable breast implants ("Mentor Saline Breast Implants" or "breast implants"). (Compl. ¶ 12.) On December 30, 2005, Plaintiff underwent surgery and Plaintiff's doctor implanted Defendant's Mentor Saline Breast Implants. (*Id.*) After the surgery, Plaintiff allegedly began to suffer from, among other things, pain throughout her body, respiratory congestion, severe fatigue, and numbness. (*Id.* ¶ 16.)

In May 2014, Plaintiff's doctors performed several tests that revealed the presence of debris and bio-toxins from mold inside of Plaintiff's breast implants. (*See id.* ¶¶ 18–19.) On May 23, 2014, Dr. Susan Kolb removed Plaintiff's breast implants, and concluded that they were leaking bilaterally. (*Id.* ¶ 20.) In June 2015, Dr. Pierre Blais examined the explanted breast implants. (*Id.* ¶ 23.) In his "Failure Analysis Report," Dr. Blais concluded that the Mentor Saline Breast Implants had defective valves, causing them to leak bilaterally. (*See id.* ¶¶ 23–30.) Dr. Blais also opined that the leaking breast implants caused Plaintiff to suffer from a variety of injuries, including: debilitating bio-toxin disease, auto-immune disorders, respiratory disease, and fibromyalgia. (*Id.* ¶ 30.)

Subsequently, Plaintiff brought this suit alleging that she has suffered injuries as a result of Defendant's manufacturing defects, negligence, and breach of warranty. (*See generally* Compl.) Initially, Plaintiff was represented by counsel, but that counsel later moved to withdraw—which this Court granted. (ECF Nos. 44, 51.) Therefore, Plaintiff is proceeding in this action pro se. (*See* ECF No. 55.) On August 4, 2017, Defendant moved to exclude the opinions of Plaintiff's proffered experts and filed the instant Motion for Summary Judgment on all of Plaintiff's claims.

III. LEGAL STANDARD

Summary judgment is appropriate under Federal Rule of Civil Procedure 56 if the moving party demonstrates the absence of a genuine issue of material fact and entitlement to a judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317,

322 (1986). A fact is material when, under the governing law, the resolution of that fact might affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute is genuine if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 249.

A party seeking summary judgment bears the initial burden to establish the absence of a genuine issue of material fact. *Celotex*, 477 U.S. at 323. To satisfy this burden, the moving party may simply point to portions of pleadings, admissions, answers to interrogatories and depositions which, along with affidavits, show the absence of a genuine issue of material fact. *See id.* If the moving party satisfies its burden, the nonmoving party must produce specific evidence to show that a genuine dispute exists. Fed. R. Civ. P. 56(e). The Court draws all inferences in the light most favorable to the nonmoving party. *See T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 630–31 (9th Cir. 1987). However, the nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986) (footnote omitted). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Liberty Lobby*, 477 U.S. at 249–50 (citations omitted).

IV. DISCUSSION

Defendant moves for summary judgment on Plaintiff's state-law claims for: (1) manufacturing defect, (2) negligence, and (3) breach of warranty. (Mot. 10.)

A. Federal Preemption Under the Medical Device Amendments of 1976 and *Riegel v. Medtronics, Inc.*

Defendant first contends that the Mentor Saline Breast Implant at issue is a Class III device approved by the Food and Drug Administration ("FDA") through the premarket approval process ("PMA process"), and thus, Plaintiff's manufacturing defect and negligence claims are expressly preempted by the Medical Device

Amendments ("MDA"), 21 U.S.C. §§ 360 *et seq*., to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*. (*See id.*)

The FDCA has long required the FDA to approve medical devices before they are introduced into the market. *Riegel v. Medtronics, Inc.*, 552 U.S. 312, 315 (2008). In 1976, Congress enacted the MDA which "swept back some state obligations and imposed a regime of detailed federal oversight" over medical devices. *Id.* at 316. Class III devices, such as the one at issue in this case, receive the most oversight. *Id.* at 317. To obtain FDA premarket approval, a manufacturer's product undergoes a rigorous application process. *Id.* After the FDA spends an average of 1,200 hours reviewing an application, a medical device receives premarket approval only if the FDA finds that "there is a reasonable assurance of the device's safety and effectiveness." *Id.* at 317–18 (internal quotations omitted). Thus, as a result of the federal government's exclusive authority to regulate and assess the safety and effectiveness of certain medical devices, the MDA contains an express preemption provision which provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In *Riegel*, the Supreme Court established the framework for analyzing express preemption under the MDA. *Riegel*, 552 U.S. at 321–24. Under the *Riegel* framework, the MDA preempts state law claims if: (1) specific federal requirements apply to the particular medical device that is the subject of the state-law claim, and (2) the state-law claim imposes a standard of care or behavior that is different from, or in

addition to the specific federal requirements. *See generally id.* (holding that MDA preemption applies to common law claims such as "strict liability, breach of implied warranty, and negligence"). Following *Riegel*, district courts in the Ninth Circuit have applied the § 360(k) preemption provision to a broad range of state-law claims brought against FDA-approved Class III medical devices, including products liability and negligence.[2]

Nevertheless, state-law claims are preempted under the MDA "only to the extent that they are different from, or in addition to, the requirements imposed by federal law." *Riegel*, 552 U.S. at 330. Thus, a State may provide remedies for state-law claims premised on violations of FDA regulations. *Id.; see also Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc) ("[T]he MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA"). To illustrate, in *Stengel*, the Ninth Circuit held that a state-law negligence claim based on a defendant's failure to report a product's performance and adverse consequences to the FDA was not expressly preempted because the "state-law duty parallel[ed the] federal law duty" to report under the MDA. *See Stengel*, 704 F.3d at 1232–33. In that case the Ninth Circuit reasoned that the state-law claim for failure to warn paralleled the federal law because it demanded the same conduct of manufacturers as the MDA—i.e., to report known risks associated with the use of its medical device to the FDA. *See generally id.*

1. **Defendant's Mentor Saline Implants Received FDA Premarket Approval**

As an initial inquiry, this Court must first determine whether specific federal requirements apply to the breast implants at issue in this case. *See Riegel*, 552 U.S.

[2] *See, e.g., Dunbar v. Medtronic, Inc.*, No. CV 14-0529-RGK(AJWx), 2014 WL 3056026 (C.D. Cal. June 25, 2014) (dismissing strict liability and design defect claims as expressly preempted because the claims conflicted with FDA premarket approval of the product); *see also Anderson v. Medtronic*, No. 14-CV-00615-BAS(RBB), 2015 WL 2115342 (S.D. Cal. May 6, 2015) (dismissing strict liability and negligence claims as expressly preempted by the MDA).

321–22. In *Riegel*, the Supreme Court reasoned that premarket approval necessarily "imposes requirements under the MDA." *Id*. at 322 (internal quotations omitted). On May 10, 2000, the FDA concluded that the Mentor Saline Breast Implants manufactured by Defendant were safe and effective Class III Medical Devices. (Statement of Uncontroverted Facts ("SUF") ¶ 8, ECF No. 59-1; *see also* FDA Approval, ECF No. 59-4.) Accordingly, the FDA issued premarket approval for the Mentor Saline Breast Implants. (SUF ¶ 8.) Furthermore, the Mentor Saline Breast Implants were manufactured and marketed pursuant to a valid PMA process, and the FDA's approval of the Mentor Saline Breast Implants has never been suspended or revoked. (*See* SUF ¶ 8; *see also* Mot. 19.) Thus, the Court finds that there are specific federal requirements that apply to the Mentor Saline Breast Implant at issue in this case and, consequently, the FDA's premarket approval for those medical devices is sufficient to establish the first prong of *Riegel*'s preemption analysis. *See Funke v. Sorin Grp. USA, Inc.*, 147 F. Supp. 3d 1017, 1023 (C.D. Cal. 2015) (finding the first prong of *Riegel*'s preemption analysis satisfied when a Class III product received FDA premarket approval and was subject to continued regulation by the FDA).

2. **Plaintiff's Claims for Manufacturing Defect and Negligence**

Next, under *Riegel*'s second prong, the Court must determine whether Plaintiff's manufacturing defect or negligence claims are based on any requirement of state law that is "different from, or in addition to" federal requirements and relate to safety and effectiveness. *See Riegel*, 552 U.S. at 323.

Plaintiff's manufacturing defect and negligence claims may survive express preemption only if she sufficiently pleads state-law claims that parallel, rather than add to, federal requirements. *See id.* To plead parallel claims sufficient to survive preemption, a plaintiff must allege facts "(1) showing an alleged violation of FDA regulations or requirements related to [the device], and (2) establishing a causal nexus between the alleged injury and the violation." *Erickson v. Bos. Sci. Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011). In its Motion, Defendant first argues that

Plaintiff fails to plead a manufacturing defect or negligence claim that parallels federal requirements because Plaintiff does not allege that Defendant deviated from any specific manufacturing requirement imposed by the FDA. (Mot. 20.) Defendant contends that, instead, Plaintiff relies on allegations that Defendant "purportedly violated vague and generic" Current Good Manufacturing Practices ("CGMPs").[3] (*Id.*)

Defendant argues that Plaintiff's attempt to establish parallel claims which are based on vague and unspecified CGMPs cannot survive express preemption. (*Id.*) The Court agrees with Defendant. "CGMPs are guidelines that do not create a federal requirement, and a claim based on alleged failure to comply with [CGMPs] fails to plead violation of a federal requirement." *Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 198 (E.D.N.Y. 2015). "To permit a claim that mandates compliance with such 'vague' standards effectively imposes 'different, or additional' requirements, and is preempted by [§ 360]." *Id.* (citation omitted); *see Simmons v. Bos. Sci. Corp.*, CV 12-7962 PA (FFMx), 2013 WL 12130261 (C.D. Cal. Jan. 14, 2013) (finding that a Plaintiff's manufacturing defect claim based on unspecified violations of CGMPs was "too generic, standing alone, to serve as the basis" for Plaintiff's claims); *see also In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009) (finding that the flexibility inherent in CGMPs demonstrates why a manufacturing defect claim based on them is not "parallel," and that "in the absence of a specific requirement in the CGMPs" . . . to hold the defendant liable for conduct would impose requirements "different from, or in addition to" those under federal law) (citations and internal quotations omitted).

Here, Plaintiff seeks to hold Defendant liable for manufacturing defects and negligence without citing to any specific violation of the CGMPs. (*See generally*

[3] Current Good Manufacturing Practices ("CGMPs") govern "the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." *Simmons v. Bos. Sci. Corp.*, CV 12-7962 PA (FFMx), 2013 WL 12130261 (C.D. Cal. Jan. 14, 2013) (citing 21 C.F.R. § 820.1(a)(1)).

Compl.) In her Complaint, Plaintiff cites to the CGMPs as a whole and states that Defendant's breast implants were not manufactured in accordance to the general provisions of the CGMPs. (*See* Compl. ¶ 35.) As established above, to hold Defendant liable for conduct in the absence of a specific federal requirement would impose requirements different from, or in addition to the federal law. *See Riegel*, 552 U.S. at 323. Plaintiff has not identified any specific requirements in the CGMPs that were purportedly violated by Defendant, nor has Plaintiff shown how those violations were related to any defect in the breast implants or negligence by Defendant. Thus, the Court finds that Plaintiff has failed to establish a parallel claim and, further, that her claims for manufacturing defect and negligence are preempted by the MDA, 21 U.S.C. §§ 360 *et seq*.

Therefore, the Court **GRANTS** Defendant's Motion for Summary on Plaintiff's claims for manufacturing defect and negligence.

B. Causation

In addition to the substantive reasoning provided above, the Court finds that Plaintiff provides no evidence of causation—a required element for her manufacturing defect and negligence causes of action.[4] *See Sanderson v. Int'l Flavors & Fragrances, Inc.*, 950 F. Supp. 981 (C.D. Cal. 1996) (stating that expert testimony is required to establish causation). Plaintiff's only evidence of causation is in the form of her three causation experts whose testimony this Court has already excluded. (*See* Order Granting Defendant's Motions to Exclude the Opinions of Dr. Susan Kolb, Dr. Pierre Blais, and Dr. Arthur Brawer.)

C. Plaintiff's Breach of Express Warranty Claim

Next, Defendant argues that Plaintiff has failed to plead a viable claim for breach of express warranty. (Mot. 32.) Plaintiff alleges that Defendant's breast

[4] *See, e.g., Bentzlin v. Hughes Aircraft Co.*, 833 F. Supp. 1486, 1490 (C.D. Cal. 1993) (observing that "[e]ven in a manufacturing defect suit, plaintiffs must prove proximate causation . . . ."); *see also Sanderson v. Int'l Flavors & Fragrances, Inc.*, 950 F. Supp. 981 (C.D. Cal. 1996) (observing that under California law causation is an essential element in a claim for negligence).

implants contained an express warranty against defects for at least ten years. (Compl. ¶ 53.) However, Defendant argues that Plaintiff is precluded from bringing a warranty claim, because she failed to satisfy the warranty conditions. (Mot. 33.) For the reasons discussed below, the Court finds that Plaintiff has not established a genuine dispute of material fact as to her breach of express warranty claim.

To prevail on a claim for breach of express warranty, a plaintiff must prove that the seller "(1) made an affirmation of fact or promise or provided a description of its goods; (2) the promise or description formed part of the basis of the bargain; (3) the express warranty was breached; and (4) the breach caused injury to the plaintiff." *Asghari v. Volkswagen Grp. of Am., Inc.*, 42 F. Supp. 3d 1306, 1333 (C.D. Cal. 2013) (citation omitted). Further, "[m]anufacturers are 'not liable for breach of express warranty merely because a product manifests recurring failures during the warranty period. Rather, the question is whether [a plaintiff] sought repairs, refunds, or replacements and if so, whether [the manufacturer] responded appropriately under the warranty.'" *Apodaca v. Whirlpool Corp.*, No. SACV 13-00725 JVS (ANx), 2013 WL 6477821, at * 9 (C.D. Cal. Nov. 8, 2013) (alterations in original) (quoting *Clark v. LG Elec. U.S.A., Inc.*, No. 13-CV-485-JM (JMAx), 2013 WL 2476145, at *4–5 (S.D. Cal. Jun. 7, 2013).

Under Defendant's limited warranty, to be reimbursed for out-of-pocket costs related to a revision surgery, a patient must: "(1) make a request for financial assistance to [Defendant's] Customer Quality; (2) have [Plaintiff's] surgeon contact [Defendant] to confirm the eligible event; (3) sign a release; and (4) submit information to [Defendant] so that [Defendant] can evaluate the claim." (SUF ¶ 83.) Plaintiff contacted Defendant twice in 2015 to make a warranty claim, but failed to satisfy the remaining conditions of Defendant's limited warranty. (*See id.* ¶ 85.) Specifically, (1) Plaintiff's physician did not contact Defendant to confirm the occurrence of a covered event, (2) Plaintiff did not provide Defendant with any information regarding the serial numbers of her breast implants, (3) Plaintiff did not

sign a release, and (4) Plaintiff's physician did not return the explanted breast implants to Defendant's Production Evaluation Department as required under the warranty. (*See id.* ¶¶ 86–88.) Additionally, Plaintiff has failed to plead facts or present evidence which demonstrates that Defendant failed to repair, refund, or replace her breast implants pursuant to the terms of the warranty. *See Apodaca*, 2013 WL 6477821, at *9. Therefore, the Court finds that Plaintiff has not proved the existence of a genuine dispute as to a material fact regarding her breach of express warranty claim. For the reasons stated above, the Court **GRANTS** Defendant's Motion for Summary Judgment on Plaintiff's claim for breach of express warranty.

V. CONCLUSION

For the reasons discussed above, the Court **GRANTS** Defendant's Motion for Summary Judgment. (ECF No. 59.) In light of this ruling, the Court **DENIES AS MOOT** the following Motions: Defendant's Motion to Strike Undisclosed Witnesses and Experts (ECF No. 75), Defendant's Motion in Limine #1 (ECF No. 76), and Defendant's Motion in Limine #2. (ECF No. 77.) The Clerk of the Court shall close the case.

IT IS SO ORDERED.

November 8, 2017

OTIS D. WRIGHT, II
UNITED STATES DISTRICT JUDGE